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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,291

09/18/2006

Roberto Tonelli

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Pearne & Gordon LLP

1801 East 9th Street

Suite 1200

Cleveland, OH 44114-3108

EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

NOTIFICATION DATE

DELIVERY MODE

08/14/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@pearne.com

dchervenak@pearne.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/554,291	<b>Applicant(s)</b> TONELLI ET AL.	
	<b>Examiner</b> Sean R. McGarry	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/02/08;10/25/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I and the "amino acid carrier" species "PKKKRKV" in the reply filed on 6/23/08 is acknowledged.

Claims 10-12 and "amino acid carrier" species other than "PKKKRKV" are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species respectively, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/23/08.

### ***Sequence Rule Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application continues to fail to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. The application discloses and recites amino acid sequences and nucleic acid sequences where there is no accompanying Sequence Identifier. The application fails to comply with 37 CFR 1.821(d). Applicant should review the application to ensure compliance with the sequence rules when responding to the instant Official Action.

***Priority***

Applicant cannot rely upon the foreign priority papers to overcome any rejection in this Official Action because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The following is an example and not meant to refer to each issue of translation in the claims. Applicant should review and amend the claims as appropriate to comply with current US practice.

The claims lack articles throughout; In claim 1, the term “filament is not an art recognized term and appears to be a mistranslation to “strand”; in Claim 2 “is an only

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sequence complementary to. . .” is unclear; in claim 4 “is conjugated in 3’ position to PNA sequence” is unclear in its context and lack of appropriate article for PNA.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al [Peptides Vol.23:1557-1565, 2002, cited by applicant).

Sun et al disclose PNA antisense oligomers with 3’ attached peptide carriers where the PNA oligomers are within the recited size range and target N-myc mRNA.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al [Peptides Vol.23:1557-1565, 2002, cited by applicant] and Cutrona et al [Nature Biotechnology Vol 18:300-303, 2000, cited by applicants].

The claimed invention is as set forth in the rejected claims.

Sun et al have taught the use of PNA antisense oligomers[12mers and 15mers] with carrier peptides attached to the 3' end of the oligomers where the PNA oligomers target and inhibit N-myc. It has been taught that carrier peptides are beneficial for cell penetration of PNA oligomers. It has also been taught that inhibition of expression of N-myc is desirable to inhibit N-myc for tumor growth inhibition. Sun et al do not teach antigen sequences targeting N-Myc and also do not teach the use of a carrier peptide PKKKRKV.

However Cutrona et al have taught the use of PNA antigene oligomers[sense] for inhibiting a desired gene. The PNA antigene oligomers of Cutrona et al were 17mers and also utilized the carrier peptide PKKKRKV. It has been taught that the use of this carrier peptide facilitates the entry of PNA oligomers into cells. Cutrona also teach the use of PNA oligomers for the inhibition of a target gene to inhibit tumor growth.

The art taken as a whole shows that the instant invention is obvious. The art has shown that it is desirable to inhibit N-myc to inhibit tumor cell growth. The prior art has

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shown a PNA antisense oligomer inhibiting N-myc expression in cells and has also shown the use of antigen [sense] PNA oligomers for use in inhibiting a desired gene. The prior art has shown that carrier peptide are beneficial for use with PNA oligomers to facilitate their delivery into cells. The prior art has specifically taught that the peptide carrier PKKKRKV is a peptide carrier that facilitates PNA oligomer entry into cells. The prior art has shown PNA oligomers of various sizes within the recited size range recited in the claims and further it is noted that the size range recited is within the art recognized sizes for the use of antisense applications for target specificity and efficient delivery. One would be motivated to make either antisense or sense PNA oligomers targeting N-myc since the art clearly shows that antisense oligomers targeting N-myc function to inhibit N-myc and since the art has shown that antigen sequences[sense] can also be used to inhibit a desired gene target. One would be motivated to utilize peptide carriers since the art has taught that such carriers are required for effective delivery into cells. One would be motivated to inhibit N-myc since the art has indicated that inhibition of N-myc can inhibit tumor growth.

The invention as a whole would therefore have been prima facie obvious to one in the art at the time the invention was made.

Claims 2, 7, 16 and 17 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry  
Primary Examiner  
Art Unit 1635

/Sean R McGarry/  
Primary Examiner, Art Unit 1635